

510(k) Summary

General Company Information

Athletic IQ, Inc.
275 Turnpike Street
Canton, MA 02021
Mark Butts, President
781-821-4114

MAY 24 2006

General Device Information

Product Name: BC100 Body Composition Analysis System

Common Name: Body fat analyzer

Classification: Impedance plethysmograph (body composition analyzer) / MNW

Predicate Devices RJI Quantum II Bioelectrical Body Composition Analyzer (K830292)
Omron BodyLogic Body Fat Analyzer (K011652)
Long-Well 6DS Body Fat Analyzer (K030203)

Indications for Use:

The BC100 Body Composition Analysis System is a noninvasive bioimpedance analyzer for use in healthy subjects for measurement of actual height, actual weight and estimated body fat percentage. The applicable age range is 10 to 80 years old.

Product Description:

The proposed Athletic IQ, Inc. (AIQ) BC100 Body Composition Analysis System is a noninvasive bioimpedance analyzer for use in healthy subjects for measurement of actual height, actual weight and estimated body fat percentage. The applicable age range is 10 to 80 years old. The device determines estimated body fat percentage based on bioelectrical impedance analysis (BIA). BIA relies on the differing behavior of biological tissues in response to an applied electrical current. Lean tissue is generally highly conductive, whereas fat tissue and bone are relatively poor conductors. By analyzing the response to electrical signals, BIA permits differentiation of fat vs. lean tissue. When combined with the subject's height and weight parameters, age, and gender, an estimated body fat percentage may be calculated using an experimentally derived algorithm.

Safety and Performance:

Substantial equivalence for this device was based on a comparison of labeling and performance characteristics as compared to the predicate devices, as well as on the results of testing to establish compliance with international standards for electrical safety and electromagnetic compatibility (IEC 60601-1 & IEC 60601-1-2). Clinical testing was conducted to establish the algorithm used by the BC100 system for estimation of percent body fat using bioelectrical impedance data.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Athletic IQ BC100 Body Composition Analysis System has been shown to be safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 24 2006

Athletic IQ, Inc.
c/o Pamela Papineau, R.A.C.
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K060552
Trade/Device Name: BC100 Body Composition Analysis System
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: February 28, 2006
Received: March 2, 2006

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

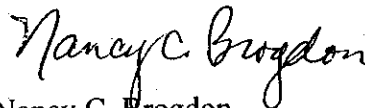
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K060552

Device Name: BC100 Body Composition Analysis System

Indications for Use:

The BC100 Body Composition Analysis System is a noninvasive bioimpedance analyzer for use in healthy subjects for measurement of actual height, actual weight and estimated body fat percentage. The applicable age range is 10 to 80 years old.

Prescription Use _____ AND/OR Over-the -Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060552

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